LIBRAMEDICAL

5. 510(K) SUMMARY

5.1 Administrative Information

MAY 2 3 2012

5.1.1 Name and address

510(k) Owner/Sponsor:
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Contour Technology
10 South 5th Street, Suite 990
Minneapolis, Minnesota 54402
Phone: 612-230-3802
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Primary Contact Person
Sara Petrie
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Date Prepared: 5/15/2012

5.1.2 Device Name

Trade Name	Contour Technology Muscle Stimulator
Common Name	Muscle Stimulator
Classification Name	Powered Muscle Stimulator with Limited Output for Muscle Conditioning
Classification	21 CFR 890.5850 Class II
Product Code	NGX
Model	MX9

5.1.3 Applicant's Name

Contour Technology
10 South 5th Street, Suite 1000
Minneapolis, Minnesota 54402
Telephone: 612-230-3801
Fax: 612-230-3810

5.1.4 Substantial Equivalence

Contour Technology Muscle Stimulator covered by this submission is substantially equivalent to other legally marketed devices namely the following:

- K011880, Compex Sport, Compex S.A.
- K031611, P4-Fitness, ValMed Corporation
- K030708, Slendertone Flex 515, Bio-Medical Research Ltd.

The Contour Technology Muscle Stimulator and the predicate devices have the same intended use and similar indications, technological characteristics and principles of operation that includes the delivery of small amount of electrical stimulation to skeletal muscles for conditioning of the muscles. There are design and engineering differences between the Contour Technology Muscle Stimulator and the predicate devices. However, these differences do not raise new questions of safety or efficacy. Specifically, the only technological difference between the Contour Technology Muscle Stimulator and its predicates is the shape of the stimulator, user interface and specific duration and pulse energy of each of the pre-set programs. These differences do not present any new issues of safety or effectiveness as the Contour Technology Muscle Stimulator is substantially similar to the three cited predicates. Further, performance testing conducted by the company demonstrates that the device meets the FDA *Draft Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Muscle Conditioning.*

Thus, the Contour Technology Muscle Stimulator is substantially equivalent to the predicate devices.

5.1.5 Device Description

The Contour Technology Muscle Stimulator is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Contour Technology Muscle Stimulator may therefore be considered a technique or method for muscle training for improvement of muscle tone, for the strengthening of the following muscles: upper back, lower/mid back, lower back, biceps, triceps, forearm-flexor, forearm-extensor, deltoids, abdominal, gluteus, hamstrings, quadriceps, and calves for the development of firmer muscles.

The electrical stimulation is delivered to the muscles through two channels. The output signal is monophasic, rectangular and based on a regulated voltage technology. The parameters (pulse rate, pulse duration, stimulation time, rest time) are optimized for each program. The power is supplied by 4 AAA batteries.

Pulses, transmitted by the Contour Technology Muscle Stimulator are sent to Gel Pad electrodes placed over the muscle region. The signal reaches out to the motor neuron that innervates the muscle fiber resulting in contraction of the muscle. The energy is delivered through 2-3 pairs of gel pads. Optional accessories are available to allow for hands free operation of the device when placed on the abdomen or back.

5.1.6 Indications for Use/Intended Use

The Contour Technology Muscle Stimulator is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Contour Technology Muscle Stimulator may therefore be considered a technique or method for muscle training.

The Contour Technology Muscle Stimulator Ab Belt accessory is intended for use on abdominal muscles only for strengthening and toning of abdominal muscles.

The Contour Technology Muscle Stimulator BackPad accessory is intended for use on the lower back muscles only.

5.1.7 Contraindications

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

5.1.8 Summary of Technological Characteristics compared to predicate devices

Technological characteristics compared to predicate devices can be found in Table 1.

Table 1: Technological Characteristics comparison

Item	Contour Technology Muscle Stimulator	Predicate: Compex Sport	Predicate: ValMed P4-Fitness	Predicate: Slendertone Flex 515
510(k) Number	K111476	K011880	K031611	K030708
Indications for Use	The Contour Technology Muscle Stimulator is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Contour Technology Muscle Stimulator may therefore be considered a technique or method for muscle training. The Contour Technology Muscle Stimulator Ab Belt accessory is intended for use on abdominal muscles only for strengthening and toning of abdominal muscles. The Contour Technology Muscle Stimulator BackPad accessory is intended for use on the lower back muscles only.	*"Compex® Sport" is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.* *"Compex® Sport"* is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the *"Compex® Sport"* training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The *"Compex® Sport"* electrical impulses allow triggering action potentials on	The P4-Fitness is intended for stimulation of healthy muscles in order to enhance and facilitate improved muscle performance. The P-4 Fitness is therefore properly considered as a technique or method for muscle training. The P4-Fitness is NOT intended for use in any therapy or for treatment of any medical conditions or diseases. The P4-Fitness training programs are not designed or intended for injured or otherwise impaired muscles and use of the P4-Fitness on such muscles is contraindicated.	The improvement of abdominal muscle tone, for the strengthening of abdominal muscles and for the development of a firmer abdomen.

Item	Contour Technology Muscle Stimulator	Predicate: Compex Sport	Predicate: ValMed P4-Fitness	Predicate: Slendertone Flex 515
		motoneurones of motor nerves (excitations). The excitations of motoneurones are transmitted to the muscle fibers via the motor endplate hwere they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles. The various types of muscles work that "*Compex® Sport*" can impose on the stimulated muscles are able to improve or facilitate muscle performance. ***"Compex® Sport"* may therefore be considered a technique of muscle training.**		
Powered Muscle Stimulator	YES	YES	YES	YES
Battery operated	Four (4) 1.5V only (AAA) alkaline	One (1) NIMH Rechargeable battery (7.2V ≈1200mA/h)	One-9V lithium, alkaline or NiMh battery	Three (3) AAA 1.5V DC batteries
Regulated	YES	YES	YES	YES

Item	Contour Technology Muscle Stimulator	Predicate: Compex Sport	Predicate: ValMed P4-Fitness	Predicate: Slendertone Flex 515
Current / Voltage				
Plastic Housing Materials	YES	YES	YES	YES
Maximum Current Density	0.55 mA (rms) / cm^2 (Smallest size electrode 40.5cm^2)	4mAmp/cm^2	1 mA (rms)/ cm^2 If electrode impedance is <100 Ω smallest size electrodes ø 3.2 cm=10cm^2	Information Not Available
Independent channels with possibility to regulate the current individually	YES	YES	YES	YES
Pulse Duration (Width)	340 µs	200 and 400 µs	200µs or 240µs for upper extremities 320 µs or 340µs for legs	Positive: 200-300 µs Interphase: 100 µs Negative: 200-300 µs
Frequency	1 to 120 Hz	1 to 120 Hz	1 to 120 Hz	45-77 Hz
Reusable Gel pads	YES	YES	YES	YES

The technological characteristics, features, specifications, materials, and indications for use of the Contour Technology Muscle Stimulator are substantially equivalent to the predicate devices.

Therefore, there are no new safety and efficacy issues raised with the Contour Technology Muscle Stimulation Device.

5.1.9 Brief Description of non-clinical tests

Non-clinical tests were performed for the Contour Technology Muscle Stimulator and a summary is provided in Table 2.

Table 2: Summary of Non-Clinical Tests

Test
System and Software Requirements Verification Testing
Environmental Testing
Safety Testing
Unit & Integration Testing
ESD / EMI Testing
Stress Testing
Shipping Testing
Simulated Use Testing (Usabililty Testing)

The performance data demonstrates that the device meets all the product specifications and included electrical output waveforms, energy density, safety and electromagnetic compatibility testing.

5.1.10 Brief Description of clinical performance data

No applicable. This device does not diagnose, cure, mitigate, treat or prevent disease or affect the function of the human body.

5.1.11 Conclusion

The Contour Technology Muscle Stimulator is substantially equivalent to the predicate devices. Test results demonstrate that the device is safe and effective for its intended use and the results support determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 23 2012

Contour Technology
% Libra Medical, Inc.
Ms. Sara Petrie
8401 73rd Avenue North, Suite 63
Minneapolis, Minnesota 55428

Re: K111476
Trade/Device Name: Contour Technology Muscle Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: May 01, 2012
Received: May 02, 2012

Dear Ms. Petrie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K111476

Device Name: Contour Technology Muscle Stimulator

Indications for Use:

The Contour Technology Muscle Stimulator is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Contour Technology Muscle Stimulator may therefore be considered a technique or method for muscle training.

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The Contour Technology Muscle Stimulator BackPad accessory is intended for use on the lower back muscles only.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111476